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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,456	05/02/2001	Marie-Francoise Rosier-Montus	3806.0505	1457

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EXAMINER	
LEFFERS JR, GERALD G	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,456	ROSIER-MONTUS, ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/23/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/23/2004 has been entered.

In the response filed 4/23/2004 an amendment to the claims was filed in which claims were amended (claims 1-3 & 5). Claims 1-3 and 5-38 are pending in the instant application.

Any rejection of record in the instant application not addressed herein is withdrawn. This action is not final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a NEW MATTER rejection made for essentially the same reasons of record with regard to "at least 300 consecutive nucleotides of SEQ ID NO: 1".**

Applicants have amended claim 1 to read "An isolated nucleic acid comprising a polynucleotide having 300 or more consecutive nucleotides of the nucleotide sequence of SEQ ID NO: 1....". There remains no literal support in the specification as filed for the specific limitation of "300 or more" consecutive nucleotides of SEQ ID NO: 1. Therefore, this limitation is impermissible NEW MATTER.

Claim 3 is further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a NEW MATTER rejection made with regard to the newly added negative limitation recited in amended claim 3.**

Claim 3 recites the negative limitation "and provided that the consecutive polynucleotides do not comprise the sequence GCCTC CCAAA GTGCT GGGAT TACAG GCAT". There is no literal support in the originally filed specification and claims for the newly added negative limitation. Therefore, amended claim 3 comprises impermissible NEW MATTER.

Response to Arguments/112 1st New Matter Rejections

Applicant's arguments filed 4/23/2004 have been fully considered but they are not persuasive. In response to similar grounds of rejection in the previous office action applicants' response essentially argues the instant specification provides inherent support for the limitations

objected to above and that case law (In re Johnson, 558, F.2d 1008 (CCPA 1977)) supports this position. The response asserts that since applicants have provided the full-length sequence for SEQ ID NOS: 1 & 3, as well as numerous examples of specific fragments within SEQ ID NOS: 1 & 3, applicants have adequately described the broad genus of fragments of SEQ ID NOS: 1 & 3 that are excluded by the newly added negative limitation within claim 3.

With regard to the amendment to claim 1 to read "300 or more", there is support in the specification as filed for several specific lengths of consecutive nucleotides of SEQ ID NO: 1 (e.g. see pages 14 and 90). For example, there is support in the specification for "200 or more" or "500 or more" so long as one interprets the phrase "a nucleotide probe or primer according to the invention will consist of and/or will comprise the fragments with a length chosen from..." as meaning "at least" or "or more" with regard the length of consecutive nucleotides of SEQ ID NOS: 1 & 3. There remains no literal or inherent support for adding the arbitrary limitation of "300 or more".

With regard to the negative limitation of claim 3, the case law does not appear to have the same fact pattern as in the instant application. According to applicants' argument, the added proviso excluded certain compounds to provide a limited genus, where 14 examples out of 26 specific examples fell within the scope of the limited genus. In the instant case, the number of embodiments that fall within the "limited" genus is far more than just 14 specific examples. SEQ ID NO: 1 is ~ 3.2 kilobases in length. SEQ ID NO: 3 is derived from and overlaps with SEQ ID NO: 1 over the entire length of SEQ ID NO: 3. Claim 3 specifies that the claimed nucleic acid comprise at least 300 nucleotides of SEQ ID NO: 1 and must further comprise at least 20 consecutive nucleotides of SEQ ID NO: 3. Thus, claim 3 encompasses an enormous

genus of nucleotide sequences that must satisfy these limitations. The additional negative limitation of excluding an arbitrary 29 base sequence from within SEQ ID NO: 3 at nucleotides 1198-1227 of SEQ ID NO: 1 does not so limit the number of fragments encompassed by resulting claim that the skilled artisan could envision the genus claimed. Therefore, there remains no literal or inherent support for the newly added negative limitation of claim 3.

Claims 15-16 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Claims 15 and 16 recite an isolated nucleic acid having at least 80% nucleotide identity to the isolated nucleic acid of claim 1. Claim 16 specifies the nucleic acid has transcriptional regulatory activity.

Claims 23 and 24 recite an isolated nucleic acid that hybridizes under high stringency conditions with the isolated nucleic acid of claim 1. Claim 24 specifies the nucleic acid has transcriptional regulatory activity.

In each case the claims are dependent upon claim 1, which recites open claim language directed to a nucleic acid comprising at least 300 consecutive nucleotides of SEQ ID NO: 1. Claim 1 encompasses *any* nucleic acid of literally *any* length so long as it comprises at least 300 consecutive nucleotides of SEQ ID NO: 1. There is no limitation in the rejected claims that the recited percent identity or hybridization is limited to any portion of SEQ ID NO: 1. This results

in a genus of nucleic acids encompassed by the claims that have little of anything to do with SEQ ID NO: 1 and for which there can be no basis for envisioning their structural/functional characteristics. For example, a nucleic acid with 80% global identity to a nucleic acid of claim 1 could actually have very little identity to SEQ ID NO: 1 if it is large enough, even though it may comprise the 300 consecutive nucleotides of SEQ ID NO: required by claim 1. Alternatively, a nucleic acid fragment hybridizing to the nucleic acid of claim 1 could do so at any portion of the nucleic acid of claim 1, including those having no identity with SEQ ID NO: 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-3, 5-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections.**

Claims 1-3 each recite the limitation of "or an isolated nucleic acid of complementary sequence". This limitation makes the claims vague and indefinite in that it is unclear whether (i) the complementary sequence needs to be complementary to the entire sequence to which it is complementary, (ii) can comprise a sequence complementary to any part of the first nucleic acid of the claim and/or (iii) can be a complementary nucleic acid that is complementary to only part of the first nucleic acid (e.g. a probe or primer of shorter length than the first nucleic acid but is 100% complementary over the length of the primer or probe). It would be remedial to amend the claim language to clearly indicate which type of complementary nucleic acid is claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner
Art Unit 1636

ggl

GERRY LEFFERS
PRIMARY EXAMINER